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Director of Program Administration  
National Organic Program  
Agricultural Marketing Service  
U.S. Department of Agriculture  
USDA–AMS–TMP–NOP  
1400 Independence Ave., SW.  
Room 4008–So., Ag Stop 0268  
Washington, DC 20250

These comments have been submitted (9/15/06) via e-mail to: [National.List@usda.gov](mailto:National.List@usda.gov),  
and via Federal Express

7 CFR Part 205  
[Docket Number TM–03–04] RIN 0581-AC62  
Reference Page 40624 of the Federal Register Vol. 71, Number 136  
Monday, July 17, 2006

**Proposed Amendments to the National List of Allowed and Prohibited Substances  
(Livestock)**

Joint comments prepared and submitted by:  
CROPP Cooperative/Organic Valley  
Horizon Organic Dairy, LLC  
Dr. Hubert Karreman, VMD

We thank the Secretary of Agriculture (Secretary) and the United States Department of Agriculture (USDA) for the opportunity to comment on the proposed amendments to the National List of Allowed and Prohibited Substances, for livestock. Among our three companies, we work with over 1,000 organic dairy farms across the United States. The materials recommended in this Federal Register notice (for use with certified organic livestock), will enable farmers to provide a higher level of humane care for their animals, and preserve the animals' organic status. We take very seriously our duty as stewards of these animals, and take very seriously the mandate in the regulations to "...not withhold medical treatment from a sick animal in an effort to preserve its organic status..."<sup>1</sup>

We would also like to thank the authors for the construction of this Federal Register notice. The inclusion of select background information, historical overview, mode of action and usages both within and outside of organic production is helpful. We also appreciate the record with reasoning that led to the language in this proposal, and hope to enjoy similarly constructed notices in the future

The materials approved by the National Organic Standards Board (NOSB) are necessary tools that have gone through a very rigorous and transparent public process. They have

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<sup>1</sup> 7 CFR Part 205, [Docket Number: TMD-00-02-FR], RIN: 0581-AA40, USDA AMS, National Organic Program 205.238(c)(7)

been discussed and vetted by the organic community over the last 6 plus years. Many of these materials were in use in organic livestock production before the National Organic Program (NOP) regulations were written.

While we wholeheartedly support the Secretary's proposals where they are true to the NOSB's recommendations, we have concerns regarding some materials where NOSB restrictive language was not adopted in the proposed regulation. Without the NOSB annotations, the usage allowances are dramatically different. We are also extremely concerned that several materials of minimal regulatory concern have not been added to the National List. Most troubling is the statement that they will "remain prohibited" for use in organic livestock production.

### **Specific Comments:**

**Calcium propionate:** We agree with considering the material an excipient.

**Magnesium hydroxide/oxide:** Please double check language; there may not be a requirement that this be dispensed by a veterinarian. Also, magnesium hydroxide may not even need to be added to the National List. The American Association of Feed Control Officials (AAFCO) lists this substance in their Feed Ingredient definition as a mineral product under 57.86, and therefore is allowed on the National List under 205.603(d) (2). Certifiers are currently allowing the use of "pink pills" under this mineral section.

**Excipients:** In general we agree with Secretary's decision on the allowance of excipients. We are eager to hear from certification agencies if they see the process of determining NADA numbers or GRAS status as being over burdensome for farmers in the field. A clear definition of an excipient in the Regulation would be very beneficial. Also, it should be noted in the regulation that excipients can occur, and are allowed, in both natural and synthetic health care treatments.

**Epinephrine:** We concur with the USDA that the substance is natural, and therefore allowed. We do appreciate the NOSB recommended annotation for epinephrine, as it made clear the allowed use in organic agriculture. Though OFPA does not require this natural material be placed on the National List, a decision to list it would allow for a specific annotation.

**Annotations:** Some of the materials proposed for addition to the National List no longer have the restrictive use, NOSB recommended annotations. We feel strongly the need for the Secretary to construct language consistent with NOSB intent. Annotations are part of the statutory authority given the NOSB by OFPA.<sup>2</sup>

We are concerned about setting a serious precedent if the Secretary rejects all restricting annotations intended by the NOSB. There are a number of materials on the National List

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<sup>2</sup> Pub.L. 101-624, codified at 7 U.S.C. §6501 et seq, and known as the Organic Foods Production Act, hereinafter, the "OFPA".

today that were added with NOSB approved restrictions on use and extended withhold times. The idea of restrictive annotations is very important in certified organic production and quite often is the deciding point when NOSB approves materials for addition to the National List.

We recognize the Secretary's concerns about additional label claims as articulated in the Federal Register notice, and offer the following solution. The staff at FARAD (Food Animal Residue Avoidance Databank) has recommended withhold times and published them in the Journal of the American Veterinary Medical Association (JAVMA). Organic regulations could contain withholding times based on adoption of FARAD numbers. USDA could double FARAD recommended withdrawal times, thereby not creating additional label claims, and respecting the heritage and specificity of the organic farming practices. Once again, this would not be an additional label claim but would be a restriction adopted by the organic sector that has precedence within the existing NOP regulation. The following numbers for milk and meat are based on a doubling of FARAD numbers:

Butorphanol— 8 day milk, 28 day meat

Xylazine— 48 hour milk, 8 day meat

Tolazoline— 96 hour milk, 16 day meat

Flunixin—144 hour milk, 42 day meat

Atropine (for pink eye/ocular issues)—6 day milk, 28 day meat

Atropine (for organophosphate poisoning)—12 day milk, 56 day meat

**Furosemide:** Though it does have a label requirement of 48 hours for milk and meat, the annotation could simply read “96 hours for both milk withholding and meat withholding.” By not constructing the annotation as “double withhold time,” the Secretary can avoid an additional label claim.

**Poloxolene:** It is important to note, per 205.238(c)(2)<sup>3</sup>, no animal drugs are allowed in the absence of illness, therefore poloxolene should be prohibited for routine use, such as an ingredient in mineral or salt blocks. The intent of the NOSB was for the material to be used for the emergency treatment of bloat only.

**Propylene Glycol:** We request that the Secretary remain in consultation on propylene glycol. The substance was recognized for its value in organic livestock health care and approved by the NOSB. Meanwhile, some farmers have been using glycerin; glycerin can be derived from natural vegetable sources. Glycerin is 100% effective and allowed; therefore as we await the Secretary's decision, it could be a potential solution to using propylene glycol. Of concern, is that glycerin is listed as a synthetic and annotation for a limiting use. We ask this to be revisited. We recognize it may require a petition, yet ask the Secretary to consider our request at this time of rulemaking.

**Moxidectin:** This substance was not petitioned as an antibiotic. FDA does not call it an antibiotic, nor does its manufacturer. We are pleased that the TAP review noted it is less harmful to dung beetles. We would ask for its addition to the National List as a

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<sup>3</sup> 7 CFR Part 205, [Docket Number: TMD-00-02-FR], RIN: 0581-AA40, USDA AMS, National Organic Program

parasiticide, and ask the Secretary to carefully review the comments submitted by Dr. Andrew Palmeter from Fort Dodge Animal Health. Our collective companies are urging more stringent pasture language in the regulation. We recognize that young stock on pasture can be susceptible to parasites; we would like to see the least toxic treatment available to organic farmers for their livestock. We also recognize that certain weather patterns bring uncommon parasite loads, such as the wet weather in the NE this year, leading to uncommon lung worm infestations. The regulations require these animals to be treated. It would be wrong to remove them from the herd for using a substance that the organic community, the NOSB, the FDA, and the manufacturer of the substance do not consider to be an antibiotic.

**Materials remaining in consultation:**

We are concerned that the materials discussed in this section were not proposed for addition to the National List. These materials are generally referred to as “allowed by regulatory discretion.” They are some of the medications best suited to an organic system, and most likely to be used by organic producers.

If the NOSB approves something for addition to the National List that is clearly allowed by FDA discretion, and the FDA has not placed that substance on 21 CFR 530.41 as prohibited for extra-label use, then any drug approved by the NOSB should be added to the National List along with the recommended annotation. All the materials in question are used in livestock production in the United States today.

We are requesting USDA revisit the following materials. They are allowed under the current regulations. They are currently being allowed by most certifiers based on the reasons listed below. **In the meantime, it is critical that the Secretary make no comment in the Regulation that these substances are specifically prohibited.**

**Activated charcoal:** Natural forms from vegetative sources are currently available. This should be allowed and need not be on the National List.

**Calcium borogluconate or calcium gluconate:** Both are classes of electrolytes and minerals; they are already allowed per the National List.

**Kaolin Pectin:** The two substances are natural and allowed in the production of certified organic food products. Kaolin is listed on 205.605 as a non-synthetic. Pectin is included on 205.606 as an agricultural product.

**Mineral Oil:** This is allowed under the regulations today. It is listed for as a topical and as a lubricant. In organic livestock production, mineral oil has typically been used to lubricate the animals’ digestive system. The annotation could remain the same and the substance could be renumbered and placed also in the 205.603(a) section. It is not absorbed into the animals’ gut.

We thank you very much for your consideration of our comments. Sincerely,

Dr. Hubert Karreman, V.M.D., for Penn Dutch Cow Care  
Jim Pierce, Certification Czar, for CROPP Cooperative/ Organic Valley Family of Farms  
Kelly Shea, VP Government and Industry Relations/Organic Stewardship, for Horizon Organic Dairy LLC

Dr. Karreman is a dairy practitioner who works with 80 plus certified organic dairy herds in Lancaster, PA. He has been in practice with organic cattle for over 11 years. Dr. Karreman also consults with hundreds of organic dairy farmers and their veterinarians across the United States.

Organic Valley/CROPP Cooperative is an 18 year old, 800 member organic cooperative. They have always taken a leadership role in the development, implementation and monitoring of organic standards. 600 of their farms are dairy, 80 egg and 35 are livestock.

Horizon Organic, founded in 1991, was the first certified organic dairy to distribute products nationally in the United States. The company remains true to its vision for a more organic planet, purchasing milk from 342 certified organic dairy farms and providing certified organic dairy products to natural foods retailers and supermarkets across the country. Horizon Organic currently has another 250 farms making the transition to organic, keeping the organic promise from our farmers to consumers.